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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,152	03/01/2004	Robert P. van Weeghel	2183-6372US	3166
24247	7590	12/04/2006		
TRASK BRITT			EXAMINER	
P.O. BOX 2550			GABEL, GAILENE	
SALT LAKE CITY, UT 84110			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/791,152	VAN WEEGHEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 September 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 18-20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 12-17 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-20 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/1/04</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group 2, claims 12-17, with traverse, filed on September 28, 2006, is acknowledged and has been entered. Claims 1-11 and 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1-20 are pending. Claims 12-17 are under examination.
  
2. Applicant traverses the restriction requirement on the grounds that Groups I and II are deemed by Applicant to be within the same fields of search, albeit classified in different classes; hence, any search for any one group would be coextensive with the other group, and would provide relevant art both groups.

Applicant's argument is not persuasive because the two groups recite a product and process of use, each one examined for its novelty, obviousness, enablement, etc. for purposes of patentability. These inventions are distinct inventions for the reasons that each group remains to encompass different structural and functional requirements, and as such, literature search for each method and kit is different. Accordingly, while searches would be expected to overlap, there is no reason to expect the searches to be coextensive, so as to provide relevant art applicable to both groups.

### *Oath/Declaration*

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3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because of inconsistencies noted in the date of filing for international application no. PCT/NL02/00579 and the foreign European application 01203341.1 upon which the benefit of priority is claimed.

***Priority***

4. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on 9/4/2001. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

***Information Disclosure Statement***

5. The Information Disclosure Statement (PTO-1449) filed March 1, 2004 is acknowledged. The EP 0 971 233 A1 reference was not considered because neither an English translation nor a statement of relevancy was provided therefor.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is vague and indefinite in reciting, "suitable" because the term is a subjective and a relative term that lacks a comparative basis for defining its metes and bounds.

Claim 12 is also confusing in reciting, "at least comprising" because the term "at least" appears to delimit what is encompassed by the open transition term "comprising."

Claim 12 has improper antecedent basis problem in reciting, "a second marker reagent ... of a red blood cell", in the second occurrence of the term. Perhaps, Applicant intends to recite, "a second marker reagent ... of the red blood cell."

Claim 13 is confusing because it is unclear how the recitation of "reactivity of said marker reagents with said cells is determined by flow cytometry," is part of a kit.

Claim 17 is vague and indefinite in reciting, "suitable" because the term is a subjective and a relative term that lacks a comparative basis for defining its metes and bounds.

Claim 17 has improper antecedent basis problem in reciting, "a second marker reagent ... of a red blood cell", in the second occurrence of the term. Perhaps, Applicant intends to recite, "a second marker reagent ... of the red blood cell."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 12-14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Golbus (US Patent 5,962,234).

Golbus discloses a kit and reagent system for identifying and differentiating subsets of erythrocytes including fetal nucleated erythrocyte. The kit comprises a first marker reactive reagent (labeled nucleic acid probes) reactive with a first component (DNA) of a red blood cell and a second marker reactive reagent (labeled anti-embryonic hemoglobin antibody or anti-hgb E) reactive with a second component (embryonic hemoglobin (hgb E or epsilon hemoglobin)) of the red blood cell. See column 15, lines 7-38. The kit may be used in determining reactivity between the components and the reagents using flow cytometry (see column 15, lines 46-54). Alternatively, the first component may be anti-hemoglobin F antibody or anti-hgb F reactive with hgb F component of red blood cells (see column 16, lines 26-34 and lines 50-60).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golbus (US Patent 5,962,234) in view of Taniguchi et al. (Carbonic anhydrase isozymes, hemoglobin-F and glutathione levels in lead-exposed workers, Clinica Chimica Acta: International Journal of Clinical Chemistry, (1975 Feb 22) Vol. 59, No. 1, pp. 29-34).

Golbus has been discussed supra. Golbus differs from the instant invention in failing to teach that the second component of red blood cell in the kit is carbonic anhydrase B. See Abstract.

Taniguchi et al. study the effect of lead in red cell components during red cell synthesis. The red cell components tested for include hgb F and carbonic anhydrase B.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate a reagent reactive to carbonic anhydrase B as used in

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the teaching of Taniguchi, into the kit taught by Golbus for determining another component of red blood cell, in this case, carbonic anhydrase B, because Taniguchi specifically taught that the reagent can be used to determine levels of carbonic anhydrase B in determining the effect of lead to synthesis of red blood cells, and Golbus and Taniguchi specifically provide that red blood cells are a complex system having different proteins that can be identified for purposes of classifying them and identifying their cell lines (hgb E or hgb F) or source (maternal or fetal) or function.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel  
Patent Examiner  
Art Unit 1641  
November 22, 2006

A handwritten signature in black ink, appearing to read "Gailene R. Gabel".